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**Chu**

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(54) **SYSTEMS, METHODS AND DEVICES RELATING TO A REMOVABLE SLEEVE FOR AN IMPLANTABLE SLING**

(75) Inventor: **Michael S. H. Chu**, Brookline, MA (US)

(73) Assignee: **Boston Scientific SCimed, Inc.**, Maple Grove, MN (US)

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See application file for complete search history.

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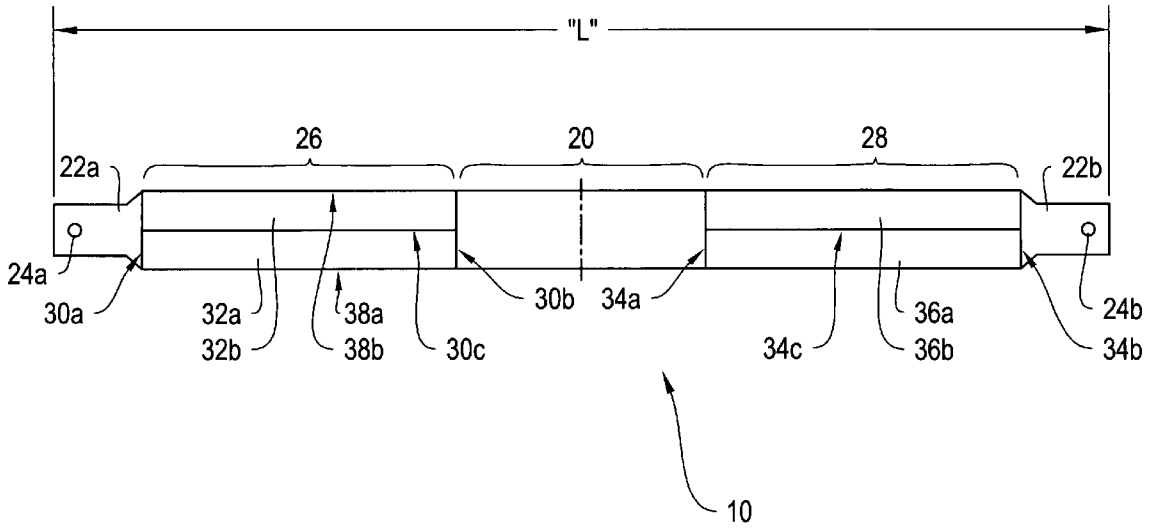
*Assistant Examiner* — Christine D Hopkins
(74) *Attorney, Agent, or Firm* — Bingham McCutchen LLP

(57) **ABSTRACT**

Devices and methods for delivering of a sling assembly and removal of the sleeve at least partially enclosing the sling through a single orifice of incision are disclosed.

**8 Claims, 12 Drawing Sheets**



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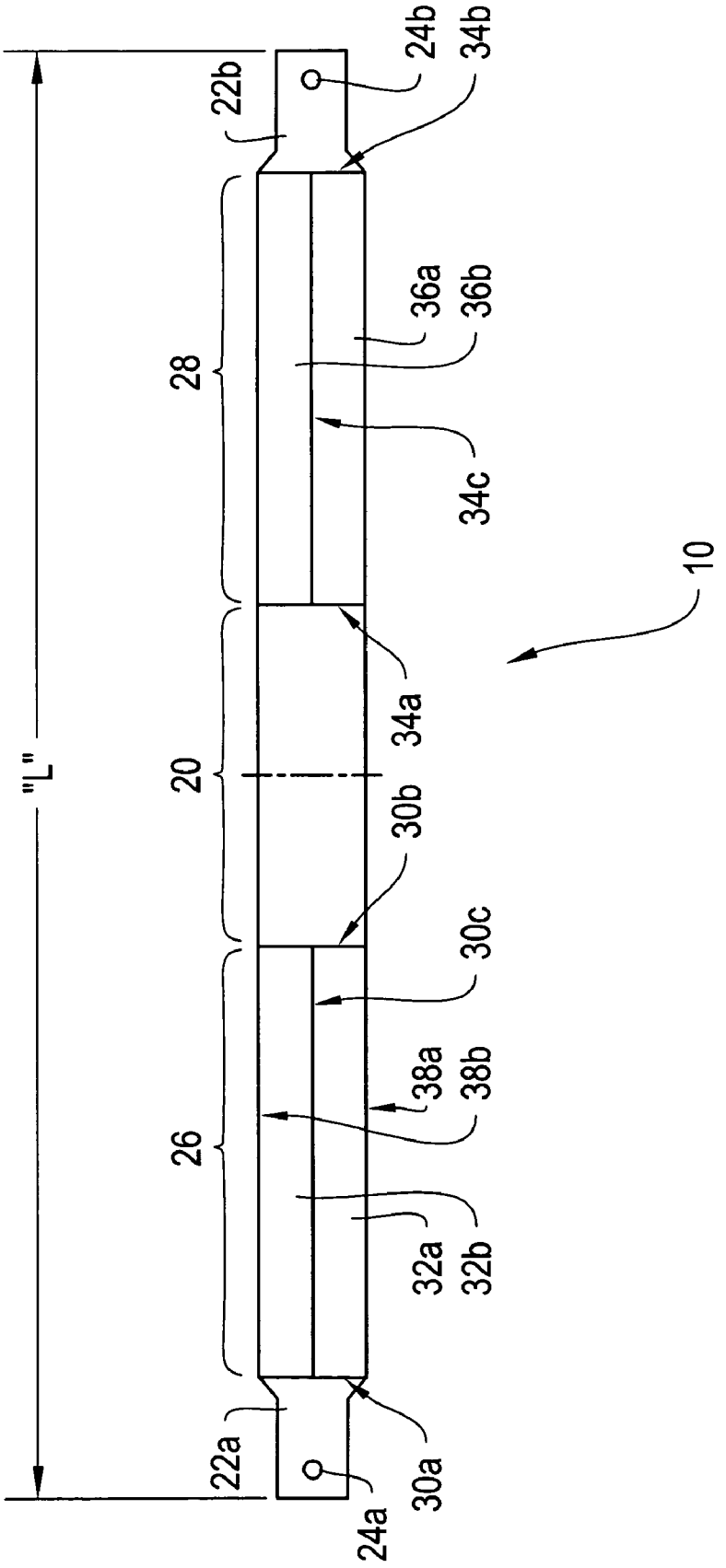
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38b
32a
32b
22a
30a
24a

FIG. 1A

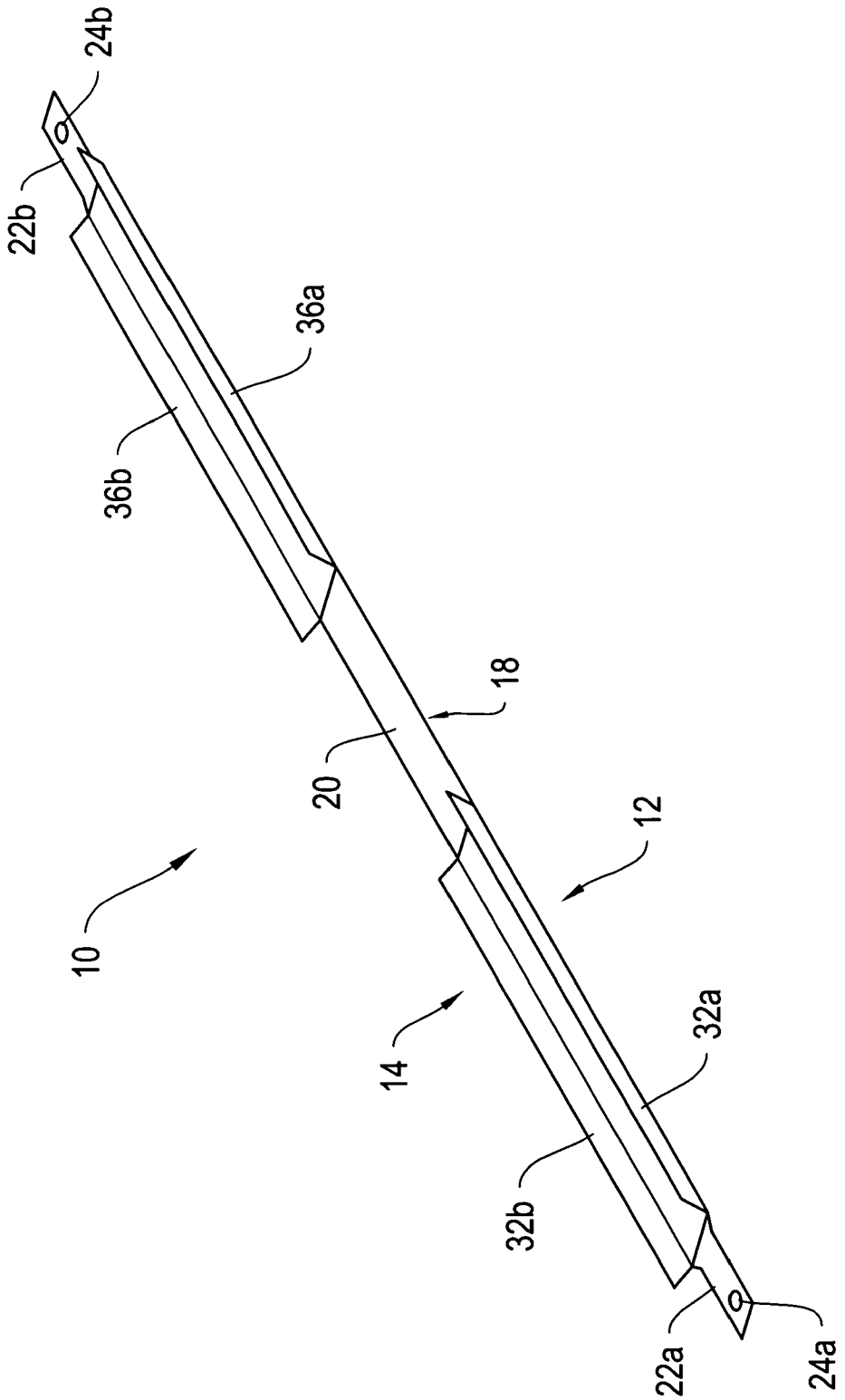



FIG. 1B

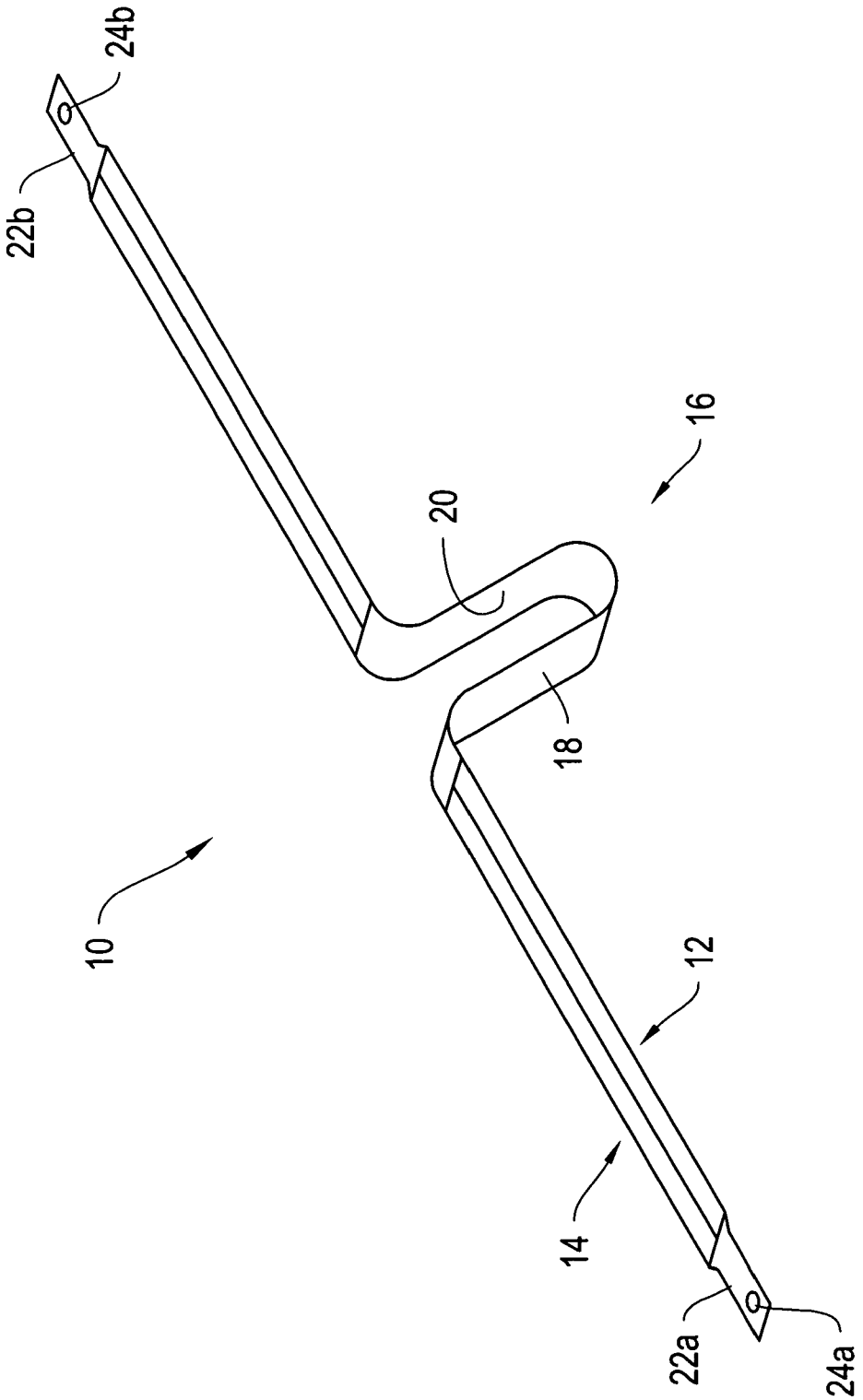



FIG. 1C

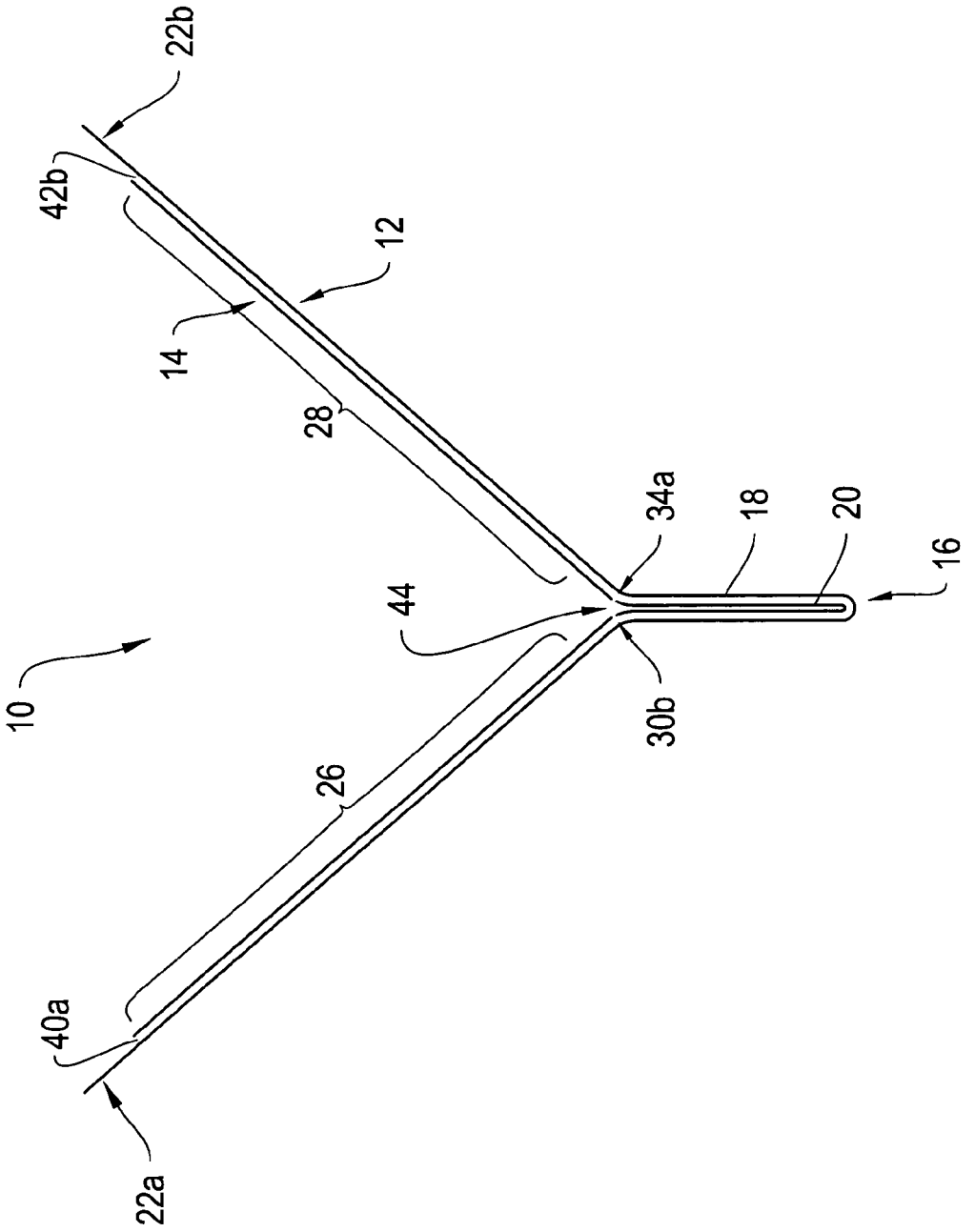



FIG. 1D

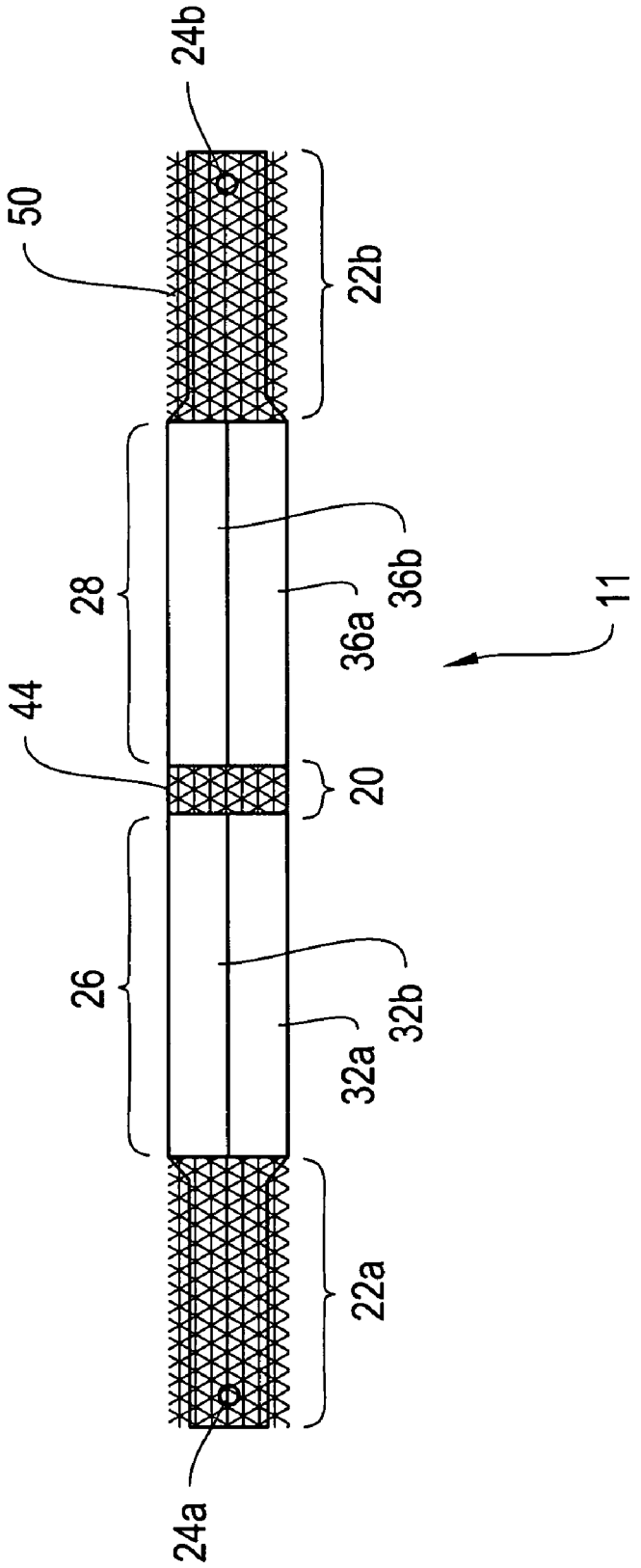



FIG. 2

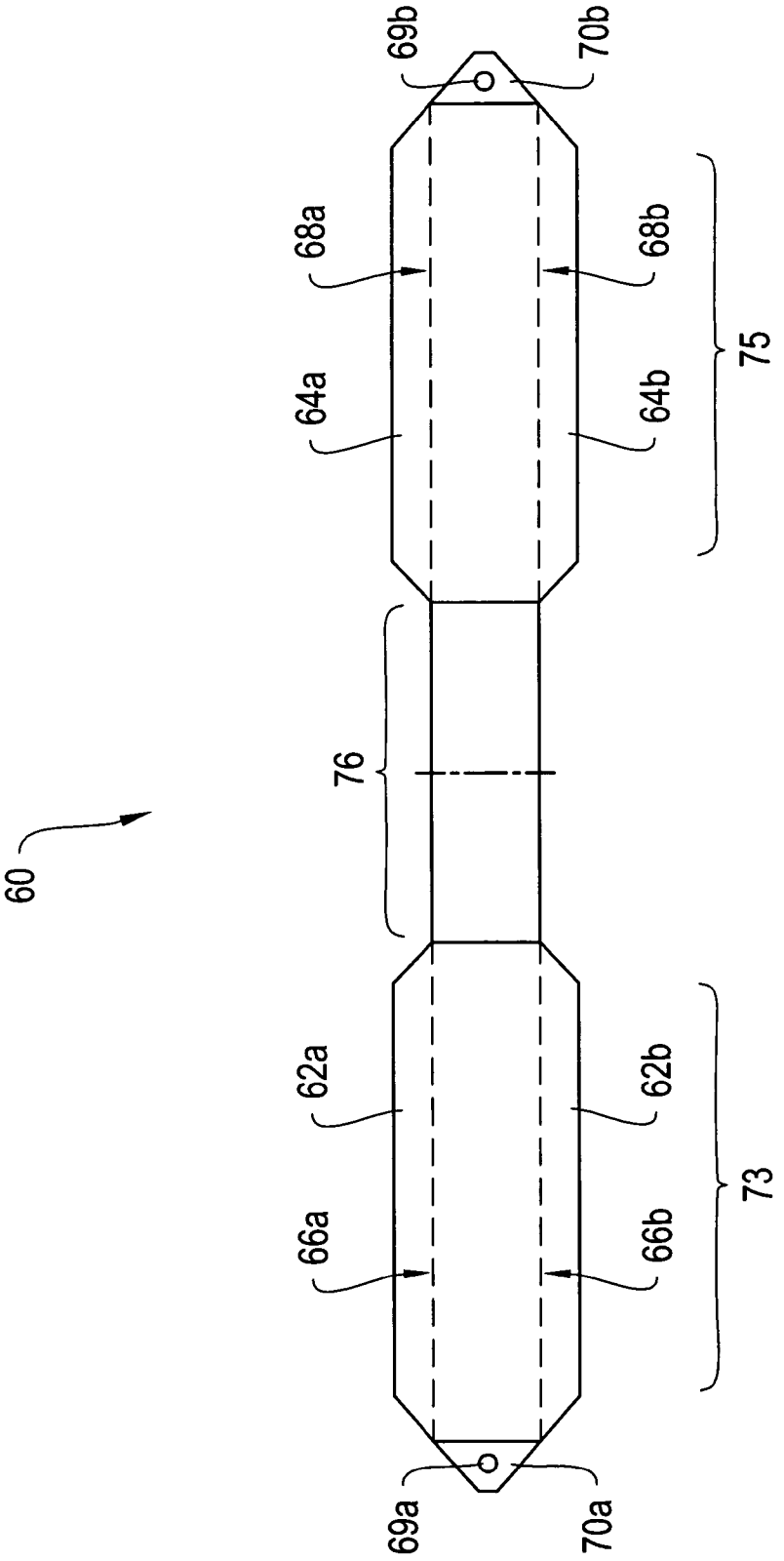



FIG. 3A

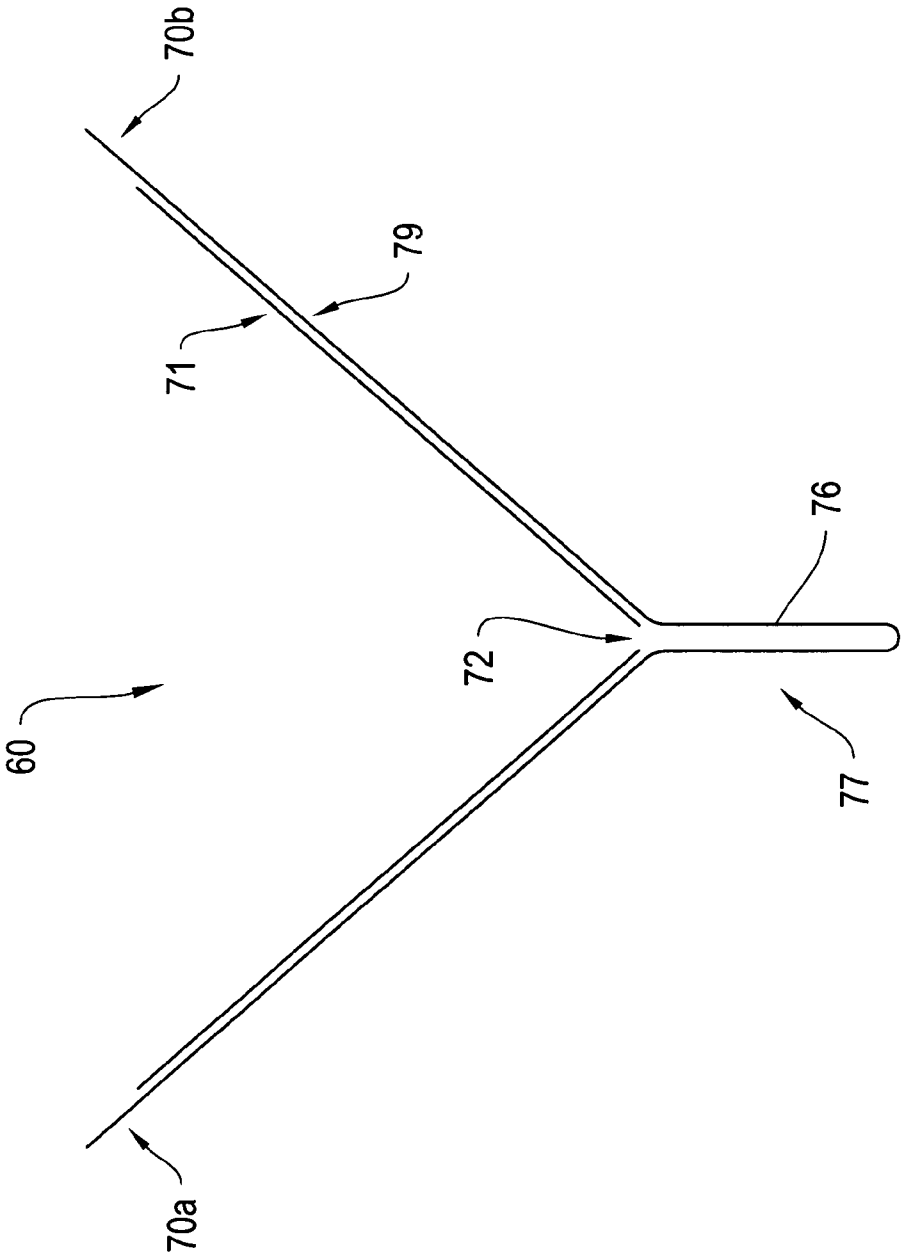



FIG. 3B

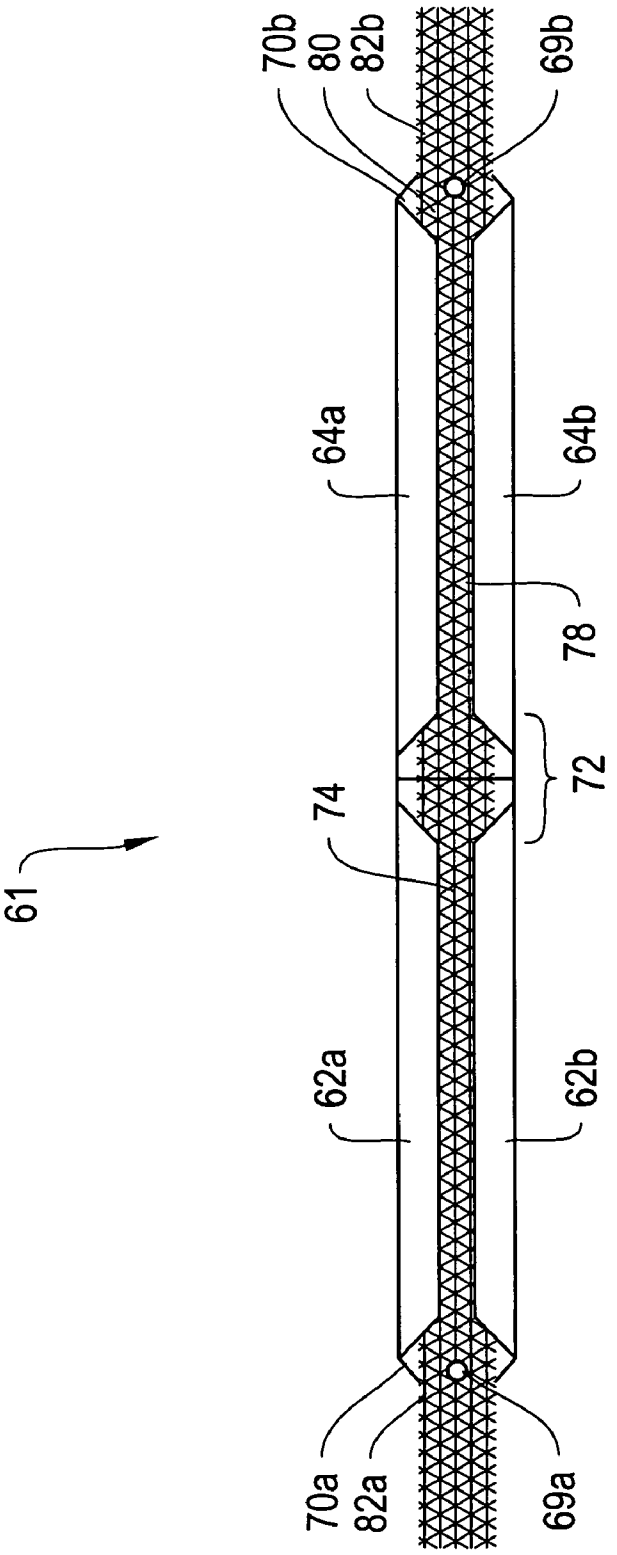



FIG. 4A

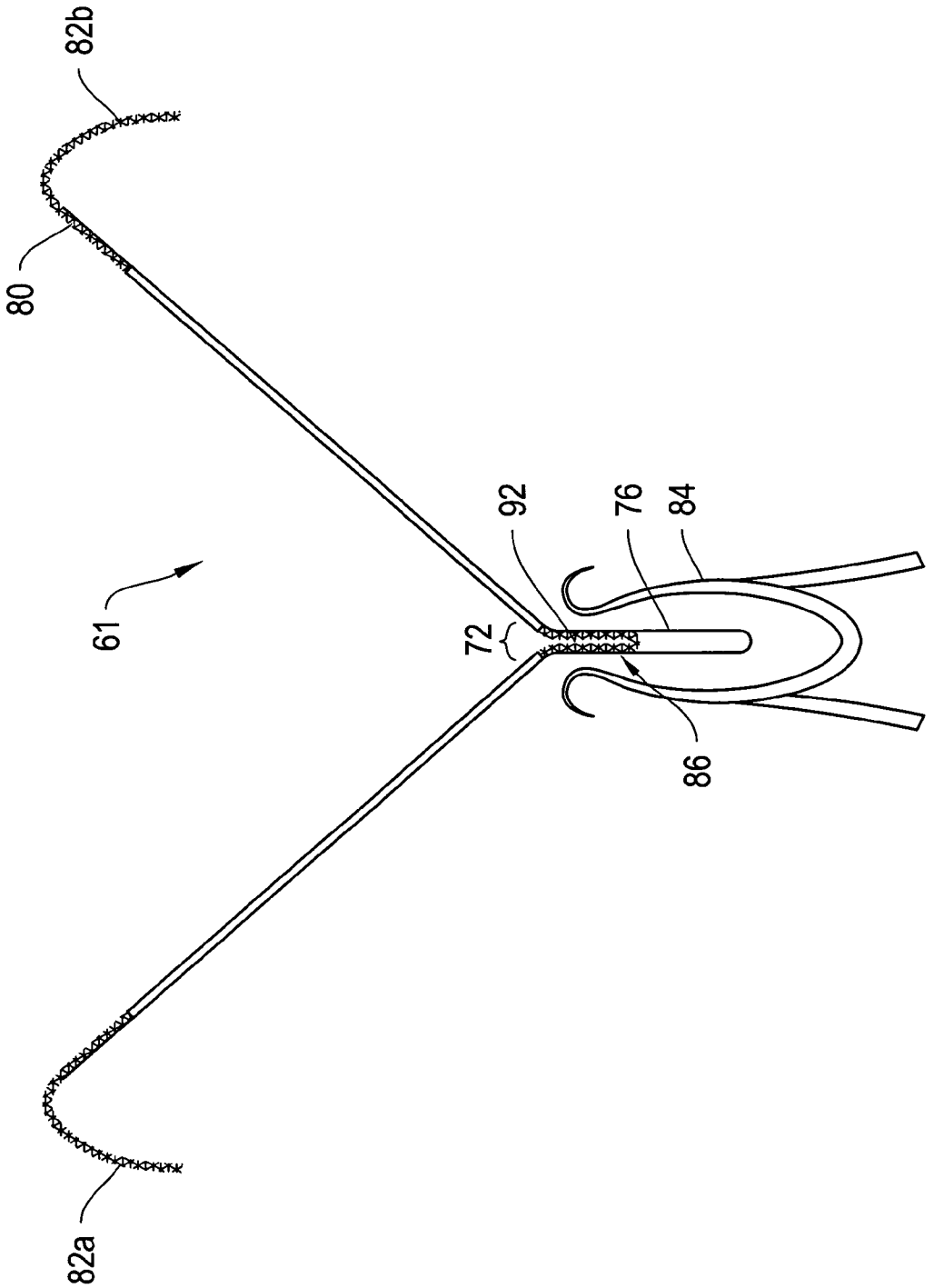
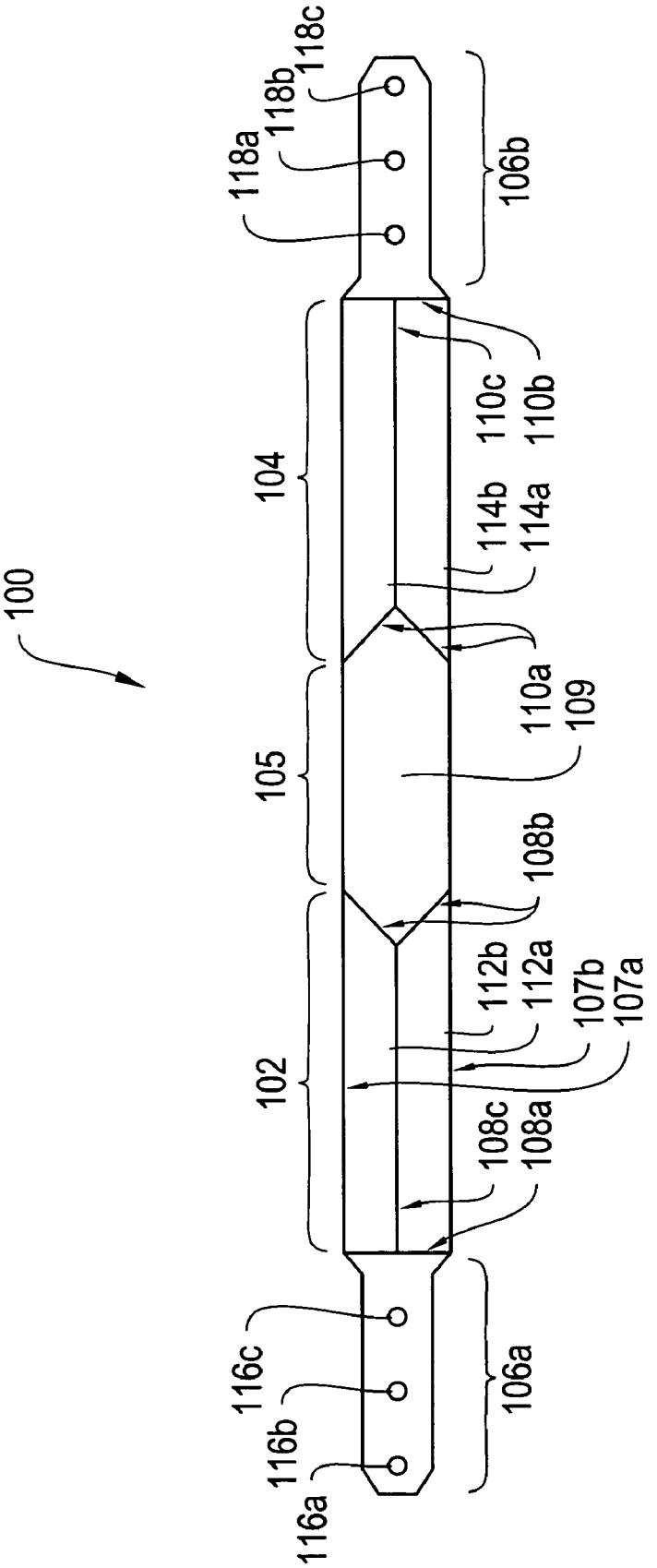



FIG. 4B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116b
116a
106a

FIG. 5

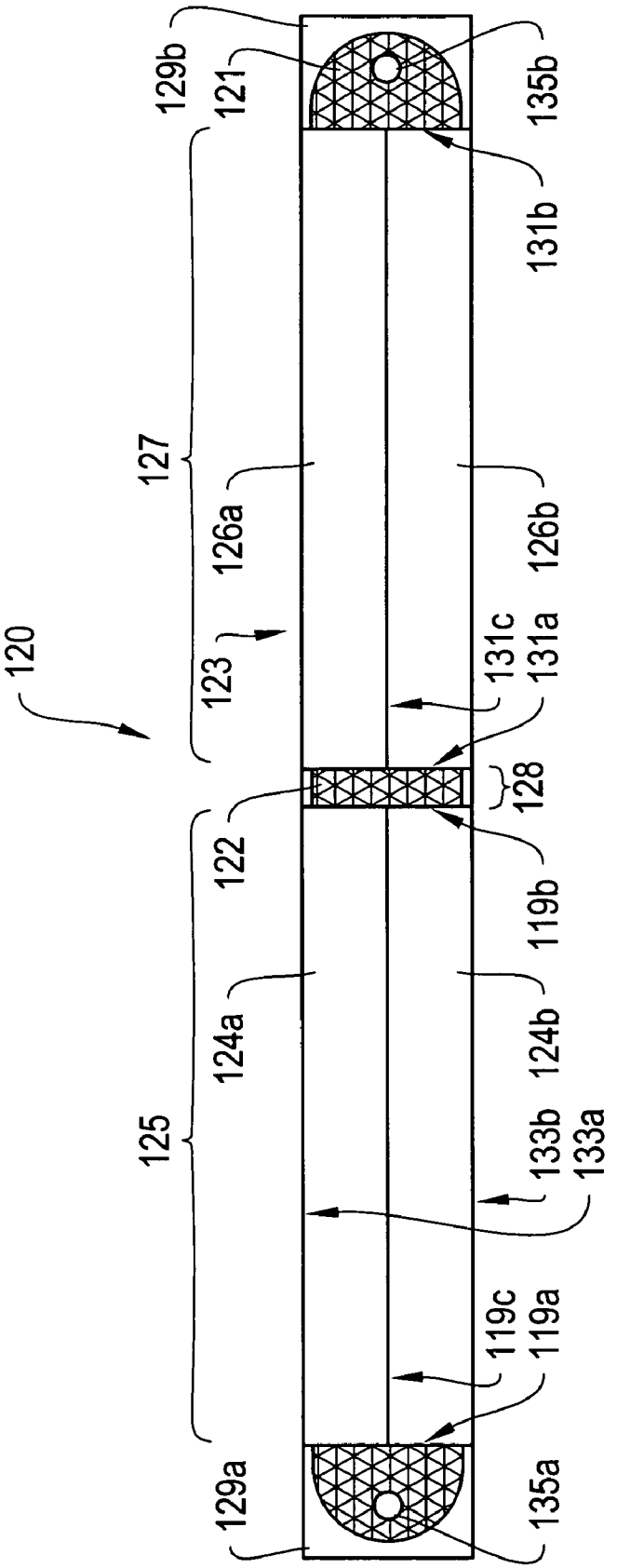
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FIG. 6

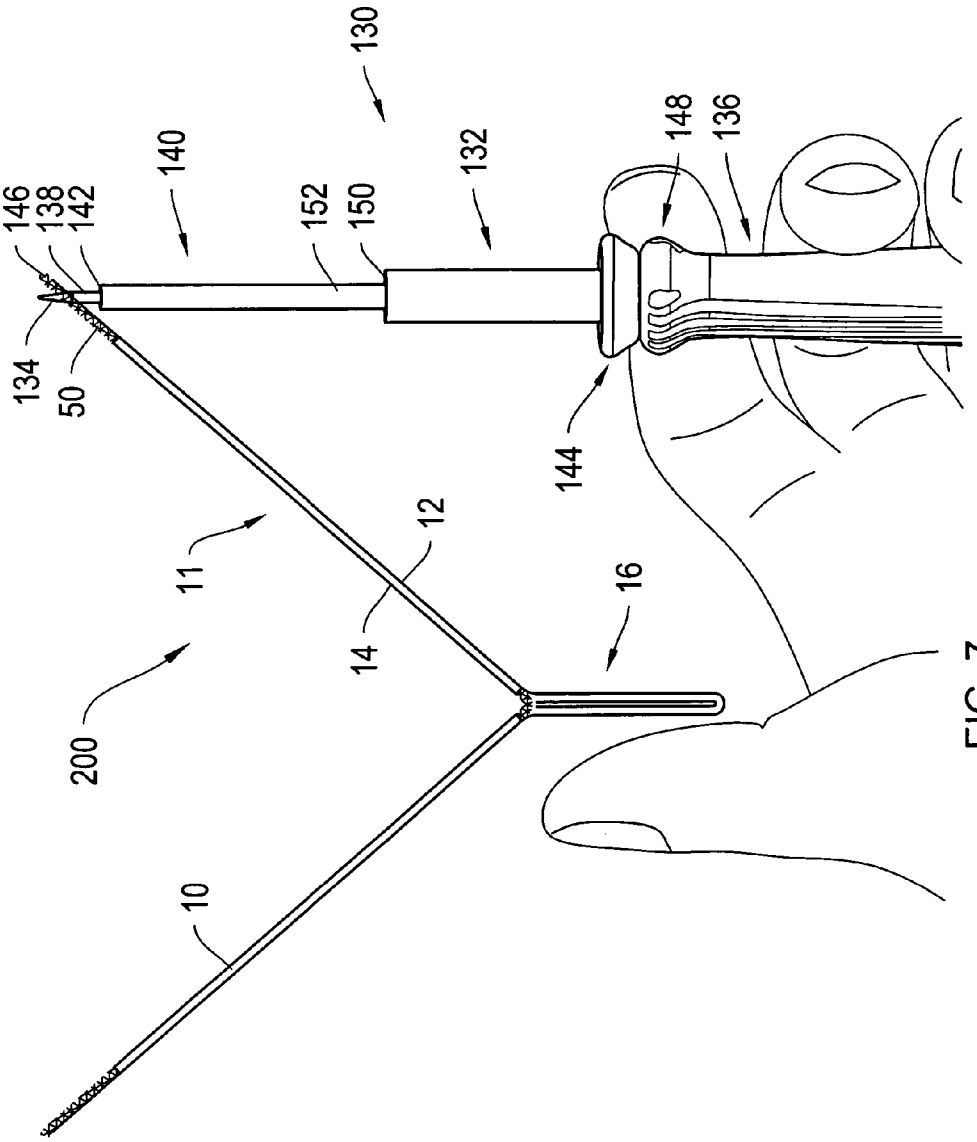
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FIG. 7

# SYSTEMS, METHODS AND DEVICES RELATING TO A REMOVABLE SLEEVE FOR AN IMPLANTABLE SLING

## FIELD OF THE INVENTION

The invention generally relates to systems and methods for delivering a supportive sling to an anatomical location in a patient. More particularly, in various embodiments, the invention relates to systems and methods for delivering a supportive sling having an easily removable sleeve to the periurethral tissue of a patient to provide urethral support.

## BACKGROUND OF THE INVENTION

Stress urinary incontinence (SUI) affects primarily women, but also men, and is generally caused by two conditions, intrinsic sphincter deficiency (ISD) and hypermobility. These conditions may occur independently or in combination. In ISD, the urinary sphincter valve, located within the urethra, fails to close properly (coapt), causing urine to leak out of the urethra during stressful activity. Hypermobility is a condition in which the pelvis floor is distended, weakened or damaged, causing the bladder neck and proximal urethra to rotate and descend in response to increases in intra-abdominal pressure (e.g., due to sneezing, coughing, straining, etc.). As a result, the patient's response time becomes insufficient to promote urethral closure and, consequently, the patient suffers from urine leakage and/or flow.

A popular treatment of SUI uses a surgical sling placed under the bladder neck or the mid-urethra to provide a urethral platform. Placement of the sling limits the endopelvis fascia drop while providing compression to the urethral sphincter to improve coaptation. The mid-urethral sling is traditionally affixed using a bone anchoring method. Recent advances in surgical techniques have demonstrated the effectiveness of anchorless approaches toward mid-urethra sling stabilization. However, these anchorless techniques typically require incisions in addition to those made in the vaginal wall. By way of example, some procedures require abdominal incisions, while others require ishiopubic incisions.

Accordingly, there is a need for an improved approach to sling placement that simplifies the procedure and reduces trauma to the patient.

## SUMMARY OF THE INVENTION

The invention addresses deficiencies of the prior art by, in one embodiment, providing systems, methods and devices for delivering a sling that is at least partially covered by an easily removable protective sleeve. According to one feature, the mechanism by which the protective sleeve is removed enables delivery of the sling through a single orifice, thereby eliminating the need for multiple incisions that cause unnecessary trauma to patients.

In one aspect, the invention provides a protective sleeve including a top layer, a bottom layer and first and second longitudinal edges. The top layer includes at least one portion having a longitudinally extending discontinuity forming at least a flap-like structure anchored along the first longitudinal edge of the sleeve. Preferably, the longitudinally extending discontinuity is located between the first and the second longitudinal edges of the sleeve, forming at least first and second flap-like structures, with the first flap-like structure anchored along the first longitudinal edge of the sleeve and the second flap-like structure anchored along the second longitudinal edge of the sleeve.



According to one embodiment, the top layer of the sleeve includes at least a first flapped section, a middle section and a second flapped section. Each of the first and the second flapped sections has a respective first longitudinally extending discontinuity forming a first flap-like structure in each flapped section. The first flap-like structure of each section is anchored along a longitudinal edge of the sleeve. According to one configuration, the middle section provides a gap on the top layer of the sleeve between the first and the second flapped sections. According to one configuration, the first longitudinally extending discontinuity of each flapped section is located along the longitudinal edge of the sleeve opposite the longitudinal edge providing the anchoring. In another configuration, the first longitudinally extending discontinuity of each flapped section is located between the first and the second longitudinal edges of the sleeve, forming first and second flap-like structures within each flapped section.

In a further embodiment, each of the first and the second flapped sections includes a transversely discontinuity extending between the first longitudinal edge and the opposing second longitudinal edge to divide each flap-like structure into at least two flap-like structures. The longitudinal ends of each of the flap-like structures may be of any suitable shape, such as straight, tapered, scallop-edged, fan-shaped or wavy.

According to another aspect of the invention, the bottom layer of the sleeve includes a first end tab at a first end of the sleeve and a second end tab at a second end of the sleeve. In one embodiment, the first end tab and the second end tab each comprises at least one through aperture for attaching to a delivery device. In an alternative embodiment, the first end tab and the second end tab each includes three through apertures, each of which is suitable for attaching to a delivery device.

According to another aspect of the invention, the sleeve includes a center tab located near a midpoint of the bottom layer of the sleeve. The center tab encloses a middle section of the bottom layer of the sleeve, and where appropriate, the middle section of the top layer of the sleeve. In one embodiment, the center tab is formed by heat seal. In another embodiment, the center tab is formed by a clip.

In another aspect, the invention provides methods for delivering a sling at least partially covered by a sleeve of the invention to an anatomical site in a patient. The methods include positioning the sling at least partially covered by a sleeve near an anatomical site, and removing the sleeve from the sling by unfolding the sleeve transversely away from the sling to deliver the sling to the anatomical site.

In a further aspect, the invention provides methods for delivering a sling at least partially covered by a sleeve of the invention to an anatomical site in a patient through a single incision. The methods include placing a sling at least partially covered in a sleeve near the anatomical site through a single body orifice, and removing the sleeve away from the sling through the same body orifice to deliver the sling to the anatomical site.

Further features and advantages of the invention will be apparent from the following description of illustrative embodiments and from the claims.

## BRIEF DESCRIPTION OF THE DRAWINGS

The following figures depict certain illustrative embodiments of the invention in which like reference numerals refer to like elements. These depicted embodiments may not be drawn to scale and are to be understood as illustrative of the invention and not as limiting in any way.

FIG. **1**A depicts a top view of a removable sleeve in its full length according to an illustrative embodiment of the invention;

FIG. **1**B depicts a perspective top view of the sleeve of FIG. **1**A;

FIG. **1**C depicts a perspective top view of a sleeve similar to the sleeve of FIG. **1**A, but configured to include a center tab formed from a looped intermediate section of the sleeve according to an illustrative embodiment of the invention;

FIG. **1**D is a side cross-sectional view of the sleeve of FIG. **1**C;

FIG. **2** depicts a sling assembly including a sleeve of the type depicted in FIGS. **1**A-**1**D partially covering a sling;

FIG. **3**A depicts a top view of a removable sleeve according to another illustrative embodiment of the invention;

FIG. **3**B depicts a side view of the sleeve of FIG. **3**A configured with a center tab formed from a looped middle section of the sleeve according to an illustrative embodiment of the invention;

FIG. **4**A depicts a top view of a sling assembly including a removable sleeve of the type depicted in FIGS. **3**A and **3**B partially covering a sling;

FIG. **4**B depicts a side view of the sling assembly of FIG. **4**A with a center tab formed from a looped middle section of a bottom layer of the sleeve according to an illustrative embodiment of the invention;

FIG. **5** depicts a top view of a removable sleeve having a similar configuration to the sleeve of FIG. **1**A and including three through apertures on each tabbed end section according to another alternative embodiment of the invention;

FIG. **6** depicts a top view of a sling assembly including a sleeve partially covering a sling according to an alternative embodiment of the invention; and

FIG. **7** schematically depicts a sling delivery system including a delivery device and a sling assembly according to an illustrative embodiment of the invention.

## ILLUSTRATIVE DESCRIPTION

In general, the invention is directed to systems and methods for the treatment of urinary incontinence. In one illustrative embodiment, the invention provides simplified devices and methods for delivering a supportive sling to an anatomical site of a patient, with reduced trauma to the patient. In a preferred embodiment, the supportive sling is sized and shaped for implantation in the periurethral tissues of a patient to provide urethral support. According to one advantage, the devices and methods of the invention allow the placement of the sling and subsequent removal of a protective sleeve at least partially covering the sling through a single incision, thus eliminating the need for multiple incisions that cause unnecessary trauma to patients. According to another advantage, the devices and methods of the invention allow the removal of the sleeve from the sling without the need for cutting any part of the sleeve, further reducing unnecessary trauma to patients during a sling placement procedure. According to another advantage, the length of the sling is adjustable to accommodate people with varying distances between the urethra and the obturator. Depending on the patients, the length of the sling can be adjusted, for example, to maximize the length of the sling attached to the obturator foramen in patients to ensure maximum anchoring strength of sling to tissue. Examples of other adjustable slings are disclosed in commonly assigned U.S. Application No. 60/649,514 entitled "Systems and Methods Relating to Anchoring a Medical Implant to Tissue" and filed on Feb. 3, 2005, the contents of which are incorporated herein by reference in their entirety.

FIGS. **1**A-**1**D depict various views of a removable sleeve **10** according to illustrative embodiments of the invention. Referring to FIGS. **1**A and **1**B, the sleeve **10** includes two tabbed end sections **22***a* and **22***b*, two flapped sections **26** and **28** and an intermediate section **20**. The intermediate section **20** is located between the two flapped sections **26** and **28**. In the illustrative embodiment of FIG. **1**A, it the intermediate section **20** is located near the middle of the sleeve **10**, but this need not be the case. The sleeve **10** also includes two layers, a bottom layer **12** and a top layer **14**. The tabbed end sections **22***a* and **22***b* include through apertures **24***a* and **24***b* sized and shaped to hook onto a distal end of a delivery device. The flapped section **26** is formed from two transversely extending cuts/discontinuities **30***a* and **30***b* and a longitudinally extending cut/discontinuity **30***c* in the top layer **14**. The transversely extending discontinuities **30***a* and **30***b* separate the flapped section **26** from the tabbed end section **22***a* and the intermediate section **20**, and interoperate with the longitudinally extending discontinuity **30***c* to create two flaps **32***a* and **32***b*. The flaps **32***a* and **32***b* are anchored along the longitudinal edges **38***a* and **38***b*, respectively, of the sleeve **10**. The flaps **32***a* and **32***b* open and close independent of each other, and are typically folded inward when the sleeve **10** is employed to at least partially cover a sling. As shown in FIG. **1**B, the flaps **32***a* and **32***b* may be opened to assist the removal of the sleeve **10** from an associated sling.

In a similar fashion, the flapped section **28** is formed from two transversely extending cuts/discontinuities **34***a* and **34***b* and a longitudinally extending discontinuity **34***c*. The transversely extending discontinuities **34***a* and **34***b* separate the flapped section **28** from the intermediate section **20** and the tabbed end section **22***b*, respectively, of the sleeve **10** and interoperate with the longitudinally extending discontinuity **34***c* to divide the flapped section **28** into two flaps **36***a* and **36***b*. In a similar fashion to the flaps **32***a* and **32***b*, the flaps **36***a* and **36***b* are anchored along the longitudinal edges **38***a* and **38***b*, respectively, of the sleeve **10**. The flaps **36***a* and **36***b* open and close independent of each other, and are typically folded inward when the sleeve **10** is employed to at least partially cover a sling, and may be opened to assist the removal of the sleeve **10** from the enclosed sling.

Although the sleeve **10** is depicted with the top layer **14** including an intermediate section **20** and tabbed end sections **22***a* and **22***b*, this need not be the case. In alternative embodiments, as shown in the sleeve **123** of FIG. **6** below, the intermediate section **20** only has the bottom layer **12**, thus eliminating the need for the transversely extending cuts **30***a*, **30***b*, **34***a* and **34***b*.

According to the illustrative embodiment of FIG. **1**A, the longitudinally extending discontinuities **30***c* and **34***c* are located substantially in the middle of the flapped sections **26** and **28**, respectively, thus dividing each of the flapped sections **26** and **28** into two substantially equally sized flaps. However, this need not be the case. In various other illustrative embodiments, the longitudinally extending discontinuities **30***c* and **34***c* may lie anywhere between the first and the second longitudinal edges **38***a* and **38***b* of the sleeve **10**. In one illustrative embodiment, the longitudinally extending discontinuities **30***c* and **34***c* are located along one of the longitudinal edges **38***a* and **38***b*, thus creating a single flap for each of the flapped sections **26** and **28**. In another illustrative embodiment, the longitudinally extending discontinuities **30***c* and **34***c* are not located in the middle of the flapped sections **26** and **28** or along the longitudinal edges **38***a* and **38***b*, thus dividing each of the flapped sections **26** and **28** into two flaps of unequal sizes. According to the illustrative embodiment of FIGS. **1**A and **1**B, the longitudinally extend-

ing discontinuity **30***c* is located along the same longitudinal axis as the longitudinally extending discontinuity **34***c*, thus resulting in flapped sections **26** and **28** that are symmetrical relative to each other. However, the longitudinally extending discontinuities **30***c* and **34***c* may be located along two different longitudinal axes, resulting in flapped section **26** and **28** that are non-symmetrical relative to each other.

In the illustrative embodiment of FIGS. **1**A and **1**B, the longitudinally extending discontinuities **30***c* and **34***c* are created by longitudinal cuts in the top layer **14** of the sleeve **10**. Alternatively, the longitudinally extending discontinuities **30***c* and **34***c* may be partial discontinuities through the top layer **14** of the sleeve **10**. According to one particular embodiment, such partial discontinuities include perforations, which can be torn, for example, by pulling on the looped portion **16** (shown in FIG. **1**C) of the sleeve **10**, subsequent to sling assembly placement in the patient's body.

The longitudinally extending discontinuities **30***c* and **34***c* may be substantially straight as shown in FIGS. **1**A-D. Alternatively, the longitudinally extending discontinuities **30***c* and **34***c* may be variously shaped so long as they generally extend along the length of the sleeve **10**. By way of example and not intended to be limiting, the discontinuities **30***c* and **34***c* may have an angled, wave-like, scalloped, fan-like or zig-zag shape.

The transversely extending discontinuities **30***a*, **30***b*, **34***a* and **34***b* may also adopt any suitable shapes. In an illustrative embodiment shown in FIG. **1**A, all of the transversely extending discontinuities **30***a*, **30***b*, **34***a* and **34***b* are substantially straight. In an alternative embodiment, one or more of the transversely extending discontinuities **30***a*, **30***b*, **34***a* and **34***b* are tapered, as shown in FIG. **3**A at **64***a*, FIG. **4**A at **64***a* and FIG. **5** at **108***b* and **110***a*.

The flapped sections **26** and **28** may also include additional transversely extending cuts/discontinuities between the sleeve edge **38***a* and **38***b*, or between the sleeve edges **38***a* and **38***b* and/or the longitudinally extending cut/discontinuity **30***c* and/or **34***c*, to further divide the flaps **32***a*, **32***b*, **36***a* and **36***b* into narrower sub-flaps, each of which being anchored along a longitudinal edge **38***a* or **38***b* of the sleeve **10**.

According to one illustrative construction, the sleeve **10** is formed from a flattened tube. The edges/creases **38***a* and **38***b* of the flat tube provides a hinge about which the flaps **32***a*, **32***b*, **36***a* and **36***b* open and close. According to the illustrative embodiment, in a closed position, the flaps **32***a*, **32***b*, **36***a* and **36***b* lay substantially flat.

To facilitate sling delivery, the sleeve **10** may include a center tab **16**. As shown in the illustrative embodiment of FIGS. **1**C and **1**D, the center tab **16** includes a looped middle section **18** of the bottom layer **12** and a looped middle section **20** of the top layer **14**. As shown in the cross-sectional view of FIG. **1**D, with the middle sections **18** and **20** of the sleeve **10** gathered to form the center tab **16**, a gap **44** for exposing a middle section of a covered sling remains. The gap **44**, for example, may be between about 0.5 cm and about 10 cm. In other embodiments, it is about 1 cm, about 2 cm, about 3 cm, about 4 cm, about 5 cm, about 6 cm, about 7 cm, about 8 cm, or about 9 cm. The middle sections **18** and **20** of the sling **10** may be secured to form the center tab **16** by any suitable mechanism. According to one illustrative embodiment, the center tab **16** is formed by placing a heat seal just underneath the openings **30***b* and **34***a*. In another illustrative embodiment, shown in FIG. **4**B, the center tab **86** includes a clip **84** for holding the middle section **76** of the sleeve **60** together. Examples of other embodiments of center tabs are disclosed in commonly assigned U.S. application Ser. No. 10/641,376, the entire contents of which are incorporated herein by reference.

FIG. **2** shows a top view of a sling assembly **11** including an implantable supportive mesh sling **50** partially covered by the sleeve **10**. As configured in FIG. **2**, the sling **50** is located on top of the bottom layer **12** in the flapped sections **26** and **28**, and on top of the top **14** and the bottom **12** layers in the tabbed end sections **22***a* and **22***b* and the intermediate section **20**. This configuration exposes the sling **50** along the tabbed end sections **22***a* and **22***b* and the intermediate section **20** of the sleeve **10**. With the flaps **32***a*, **32***b*, **36***a* and **36***b* closed, the sling **50** is essentially sandwiched between the top layer **14** and the bottom layer **12** of the sleeve **10** along the flapped sections **26** and **28**. Although the sling **50** is depicted as being a mesh sling, any suitable implantable sling may be employed. Preferably the sleeve **10** is formed from a flexible polymer plastic and independent from the sleeve **10**. However, any suitable sleeve material may be employed. According to the illustrative embodiment, the sling **50** does not attach to the sleeve **10**, but is instead freely moveable and independent from the sleeve. However, in alternative embodiments, the sling **50** may attach to the sleeve **10** at one or more locations.

In the illustrative embodiment of FIG. **2**, the sling **50** has a length of about 10 cm to about 45 cm and a width of about 1 cm to about 3 cm, though the length and width of the sling can be adapted to the body part of the patient that requires support. By way of example, in some embodiments, the sling is about 45 cm in length and about 1.5 cm in width. The sling may be rectangular, as illustrated in FIG. **2**, or have another suitable shape. The sling may have a uniform thickness over the entire length and/or width of sling, or the thickness may vary at one or more locations. According to the illustrative embodiment, the thickness of the sling material ranges from about 2 mm to about 0.10 cm. Additionally, the walls of the sleeve **10** are between about 1 mm to about 0.005 mm thick or about 0.039 inches to about 0.002 inches thick. The flapped sections **26** and **28** have a length of between about one-third and about one-fourth of the length of the sleeve **10**. The illustrative flapped sections **26** and **28** are between about 15 cm long and each flap **32***a*, **32***b*, **36***a* and **36***b* is about 1.5 cm wide. The middle gap **44** is shown as it would be with the center tab **16** formed as shown in FIG. **1**D. According to the illustrative embodiment of FIG. **2**, the sling **50** is a strip of mesh with any of a number and/or configurations of knits, weaves, or braids, and is sized and shaped for placement in the periurethral tissues of a patient to provide a urethral platform to treat urinary incontinence.

In the illustrative embodiment of FIG. **2**, the sleeve **10** and the sling **50** are depicted as being approximately the same length. However, this need not be the case, with the sling **50** being longer or shorter than the sleeve **10** in various other illustrative embodiments. The illustrative flapped sections **26** and **28** are between about 15 cm long and each flap **32***a*, **32***b*, **36***a* and **36***b* is about 1.5 cm wide. The middle gap **44** is shown as it would be with the center tab **16** formed as shown in FIG. **1**D.

As depicted, the sling **50** does not include any apertures particularly formed for hooking onto a delivery device. In this configuration, one or more of the mesh openings may be used for such purpose. According to one illustrative embodiment, the mesh openings employed for such a purpose are spaced two or more openings from the sling ends to provide increased structural integrity and to avoid tearing at a mesh end. In other illustrative embodiments, the sling **50** may include particularly formed apertures aligned with the aper-

tures **24***a* and **24***b* in the end tabs **22***a* and **22***b*, respectively, for hooking onto a delivery device. In this configuration, it is also advantageous to space the apertures between about 0.25 cm and about 1 cm from the ends of the sling **50**.

FIGS. **3**A and **3**B depict a sleeve **60** according to an alternative embodiment of the invention. Referring to the top view of the sleeve **60** shown in FIG. **3**A, it includes two tabbed end sections **70***a* and **70***b*, two flapped sections **73** and **75**, and a middle section **76**. The sleeve **60** is formed from a single layer, and may, for example, be made from a single flat sheet of material. The two tabbed end sections **70***a* and **70***b* include through apertures **69***a* and **69***b* sized and shaped to hook onto a distal end of a delivery device. The flapped sections **73** and **75** are formed by folding the single layer **79** of the flat sheet material along the dotted lines **66***a*, **66***b*, **68***a* and **68***b*, forming four flaps **62***a*, **62***b*, **64***a* and **64***b*, respectively. Each flap **62***a*, **62***b*, **64***a* and **64***b* opens and closes independent of each other, and is typically folded inward to form a partial top layer **71** to at least partially covering a sling. The flaps **62***a*, **62***b*, **64***a* and **64***b* open to assist the removal of the sleeve **60** from an associated sling. The width of the flaps **62***a*, **62***b*, **64***a* and **64***b* may vary. In one illustrative embodiment, shown in FIG. **4**A, when the flaps **62***a*, **62***b*, **64***a* and **64***b* are closed, neither flap pair **62***a* and **62***b*, nor flap pair **64***a* and **64***b* abut each other. Instead, gap **78** extends longitudinally between them, exposing longitudinally an extending intermediate portion of the sling **80**. In an alternative embodiment, when the flaps **62***a*, **62***b*, **64***a* and **64***b* are closed, the flap **62***a* may abut or overlap with the flap **62***b*, and the flap **64***a* may abut or overlap with the flap **64***b* and thus leaving no longitudinally extending gap. The shapes of the flaps **62***a*, **62***b*, **64***a* and **64***b* may also vary. In the illustrative embodiment of FIG. **3**A, each of the flaps **62***a*, **62***b*, **64***a* and **64***b* and the end tabs **70***a* and **70***b* have tapered ends for easy insertion and removal of the sleeve **60** from a sling that it at least partially covers. However, this need not be the case. The flaps **62***a*, **62***b*, **64***a* and **64***b* and the end tabs **70***a* and **70***b* may adopt any suitable shape as described above with respect to FIGS. **1**A-**1**D. The longitudinally and transversely extending edges of the flaps **62***a*, **62***b*, **64***a* and **64***b* and the end tabs **70***a* and **70***b* may be of any suitable shape, including without limitation straight, tapered, or may be wavy, scalloped, fan-shaped, rounded or zig-zag shaped. As shown in FIG. **3**A, the flaps **62***a*, **62***b*, **64***a* and **64***b* are of identical shapes and sizes. However, this need not be the case. In various other illustrative embodiments, the flaps **62***a*, **62***b*, **64***a* and **64***b* are of different shapes and sizes from each other.

In a similar fashion to the sleeve **10**, to facilitate sling delivery, the sleeve **60** may include a center tab **77**. As shown in the illustrative embodiment of FIG. **3**B, the center tab **77** includes a looped middle section **76** of the sleeve **60**. With the middle section **76** of the sleeve **60** gathered to form the center tab **77**, a gap **72** for exposing a middle section of a covered sling remains. The gap **72**, for example, may be between about 0.5 cm and about 10 cm. In other embodiments, it is about 1 cm, about 2 cm, about 3 cm, about 4 cm, about 5 cm, about 6 cm, about 7 cm, about 8 cm, or about 9 cm. The middle section **76** of the sleeve **60** may be secured to form the center tab **77** by any suitable mechanism. According to one illustrative embodiment, the center tab **77** is formed by placing a heat seal just underneath the gap **72**. In another illustrative embodiment, shown in FIG. **4**B, the center tab includes a clip for holding the middle section **76** of the sleeve **60** together. As shown in FIG. **3**B, the sleeve **60** includes a bottom layer **79** and at least a partial top layer **71**, which is formed when the flaps **62***a*, **62***b*, **64***a* and **64***b* are closed.

FIG. **4**A and FIG. **4**B depict a top view and a side view, respectively, of a sling assembly **61** including an implantable supportive mesh sling **80** partially covered by the sleeve **60**. According to this illustrative embodiment, the sling **80** is longer than the sleeve **60**, with the ends **82***a* and **82***b* of the sling **80** overhanging the sleeve **60**. As shown, the sling **80** is located on top of bottom layer **79** of the sleeve **60**. The flaps **62***a*, **62***b*, **64***a* and **64***b* fold over to partially sandwich the sling **80** between the flaps **62***a*, **62***b*, **64***a* and **64***b* and the bottom layer **79** of the sleeve **60**. A gap **72**, located between the flap pairs **62***a*, **62***b* and **64***a* and **64***b*, exposes the entire width of a middle section of the sling **80**. The sling **80** is additionally exposed along the tabbed end sections **70***a* and **70***b*.

FIG. **4**B also shows an alternative approach to forming a center tab **86**. Instead of the heat seal of FIG. **1**D, a clip **84** holds the looped middle section **76** of the sleeve **60** together to form the center tab **86**. This embodiment may be used in connection with any of the sleeves of the invention, including, the protective sleeve **10** shown in FIGS. **1**A-**1**D and the protective sleeve **60** shown in FIGS. **3**A and **3**B. According to the illustrative embodiment, the clip **84** also captures a looped portion **92** of the sling **80**. A medical operator may adjust the length of the loop portion **92** of the sling **80** prior to its placement to adjust the length and/or tensioning of the sling **80**. Illustratively, to prevent over tensioning of a sling, a medical operator places a hemostat, a scissors or other type of spacer between the urethra and the sling during the sling placement to ensure ample looseness of the sling. The looped portion **92** of the sling **80** eliminates the need for a spacer during placement. The looped portion **92** should generally equal to the length of the mesh sling that would have been provided by a spacer.

FIG. **5** depicts a top view of a removable sleeve **100** according to another illustrative embodiment of the invention. The sleeve **100** includes two layers, a top layer **101** and a bottom layer **103**. The top layer **101** of the sleeve **100** includes two flapped sections **102** and **104**, and a gap **105** in the middle between the flapped sections **102** and **104**, exposing the middle section **109** of the bottom layer **103** of the sleeve **100**. The flapped section **102** is formed from two transversely extending discontinuities **108***a* and **108***b* and a longitudinally extending cut/discontinuity **108***c* in the top layer **101**. The transversely extending discontinuities **108***a* and **108***b* interoperate with the longitudinally extending cut/discontinuity **108***c* to create two flaps **112***a* and **112***b*. The flaps **112***a* and **112***b* are anchored along the longitudinal edges **107***a* and **107***b*, respectively, of the sleeve **100**. The flaps **112***a* and **112***b* open and close independent of each other, and are typically folded inward when the sleeve **100** is employed to at least partially cover a sling. The flaps **112***a* and **112***b* may be opened to assist the removal of the sleeve **100** from an associated sling.

In a similar fashion, the flapped section **104** is formed from two transversely extending discontinuities **110***a* and **110***b* and a longitudinally extending cut/discontinuity **110***c* in the top layer **101**. The transversely extending discontinuities **110***a* and **110***b* interoperate with the longitudinally extending discontinuity **110***c* to create two flaps **114***a* and **114***b*. The flaps **114***a* and **114***b* are anchored along the longitudinal edges **107***a* and **107***b*, respectively, of the sleeve **100**. The flaps **114***a* and **114***b* open and close independent of each other, and are typically folded inward when the sleeve **100** is employed to at least partially cover a sling. The flaps **114***a* and **114***b* may be opened to assist the removal of the sleeve **100** from an associated sling.

The bottom layer **103** of the sleeve **100** includes two tabbed end sections **106***a* and **106***b*. Each of the tabbed end sections **106***a* and **106***b* includes three through apertures **116***a*, **116***b*,

116*c*, and 118*a*, 118*b* and 118*c*, respectively, which through apertures are sized and shaped to hook onto a distal end of a delivery device. The three through apertures allow for adjustment of the length of a sling, such as the sling **80**. If a longer sling is desired, a delivery device can be inserted into the through apertures **116***a* and **118***c* of the sleeve **100** and through a corresponding aperture or a corresponding mesh opening in the sling at least partially covered by the sleeve **100**. Alternatively, if a shorter sling is desired, a delivery device can be inserted into the through apertures **116***c* and **118***a* of the sleeve **100** and through a corresponding aperture or a corresponding mesh opening in the sling at least partially covered by the sleeve **100** and the excess sling and sleeve **100** can be trimmed off before sling placement, thus shortening the sling length. The through apertures **116***a*, **116***b*, **116***c*, and **118***a*, **118***b* and **118***c* may be, for example, 0.25 cm and 2 cm apart. In other embodiments, they are about 0.5 cm, about 1 cm or about 1.5 cm apart. In an alternative illustrative embodiment, the excess sling and sleeve can be left overhanging the delivery device and inserted into the body. In certain other illustrative embodiments, the tabbed end sections **106** and **106***b* of the sleeve **100** may each have two through apertures or have more than three through apertures.

The sleeve **100** is depicted with the middle section **109** and the two tabbed end sections **106** and **106***b* having only the bottom layer **103**, thus the discontinuities **108***a*, **108***b*, **110***a* and **110***b* are just the ends of the top layer **101**, not cuts. In alternative embodiments, the top layer **101** of the sleeve **100** includes a middle section and two tabbed end sections, thus necessitates the need for transverse cuts in the top layer **101** that create the transverse discontinuities **108***a*, **108***b*, **110***a* and **110***b*.

According to the illustrative embodiment of FIG. **5**, the longitudinally extending discontinuities **108***c* and **110***c* are located substantially in the middle of the flapped sections **102** and **104**, respectively, thus dividing each of the flapped sections **102** and **104** into two substantially equally sized flaps. However, this need not be the case. In various other illustrative embodiments, the longitudinally extending discontinuities **108***c* and **110***c* may lie anywhere between the first and the second longitudinal edges **107***a* and **107***b* of the sleeve **100**. In one alternative embodiment, the longitudinally extending discontinuities **108***c* and **110***c* are located along one of the longitudinal edges **107***a* and **107***b*, thus creating a single flap for each of the flapped sections **102** and **104**. In another illustrative embodiment, the longitudinally extending discontinuities **108***c* and **110***c* are not located in the middle of the flapped sections **102** and **104**, thus dividing each of the flapped sections **102** and **104** into two flaps of unequal size. According to the illustrative embodiment of FIG. **5**, the longitudinally extending discontinuity **108***c* is located along the same longitudinal axis as the longitudinally extending discontinuity **110***c*, thus resulting in flapped sections **102** and **104** that are symmetrical relative to each other. However, the longitudinally extending discontinuities **108***c* and **110***c* may be located along two different longitudinal axes, resulting in flapped section **102** and **104** that are non-symmetrical relative to each other.

In the illustrative embodiment of FIG. **5**, the longitudinally extending discontinuities **108***c* and **110***c* are created by longitudinal cuts in the top layer **101** of the sleeve **100**. Alternatively, the longitudinally extending discontinuities **108***c* and **110***c* may be partial discontinuities through the top layer **101** of the sleeve **100**. According to one embodiment, such partial discontinuities include perforations, which may be torn, for example, by pulling on a looped portion formed from the middle section **109** of the sleeve **100**, subsequent to sling assembly placement.

The longitudinally extending discontinuities **108***c* and **110***c* may be substantially straight as shown in FIG. **5**. Alternatively, the longitudinally extending discontinuities **108***c* and **110***c* may be variously shaped so long as they generally extend along the length of the sleeve **100**. By way of example and not intended to be limiting, the discontinuities **108***c* and **110***c* may have an angled, wave-like, scalloped, fan-like or zig-zag shape.

The transversely extending discontinuities **108***a*, **108***b*, **110***a* and **110***b* may also adopt any suitable shapes. In the illustrative embodiment of FIG. **5**, the transversely extending discontinuities **108***a* and **110***b* are substantially straight, while the transversely extending discontinuities **108***b* and **110***a* are tapered in shape. The flapped sections **102** and **104** may also include additional transversely extending cuts/discontinuities between the sleeve edge **107***a* and/or **107***b* and the longitudinally extending cut/discontinuity **108***c* and/or **110***c*, or extending between the sleeve edges **107***a* and **107***b*, to further divide the flaps **112***a*, **112***b*, **114***a* and **114***b* into narrower sub-flaps, each of which being anchored along a longitudinal edge **107***a* and **107***b* of the sleeve **100**.

According to one illustrative embodiment, the sleeve **100** is formed from a flattened tube. The edges/creases **107***a* and **107***b* of the flat tube provide a hinge about which the flaps **112***a*, **112***b*, **114***a* and **114***b* open and close. In a closed position, the flaps **112***a*, **112***b*, **114***a* and **114***b* lay substantially flat.

FIG. **6** shows a top view of a sling assembly **120** including an implantable supportive mesh sling **121** partially covered by the sleeve **123** according to another illustrative embodiment of the invention. The sleeve **123** is configured similarly to the sleeve **10** shown in FIGS. **1A-1D**. The sleeve **123** includes two layers, a top layer and a bottom layer. The top layer of the sleeve **123** includes two flapped sections **125** and **127** and a gap **122**, between the two flapped sections **125** and **127**, which corresponds to the middle section **128** of the bottom layer of the sleeve **123**. The bottom layer of the sleeve **123** includes a middle section **128** and two tabbed end sections **129***a* and **129***b*, each of which includes a through aperture **135***a* and **135***b*, respectively sized and shaped to hook onto a distal end of a delivery device. The flapped section **125** is formed from two transversely extending discontinuities **119***a* and **119***b* and a longitudinally extending cut/discontinuity **119***c* in the top layer of the sleeve **123**. The transversely extending discontinuities **119***a* and **119***b* interoperate with the longitudinally extending discontinuity **119***c* to create two flaps **124***a* and **124***b*. The flaps **124***a* and **124***b* are anchored along the longitudinal edges **133***a* and **133***b*, respectively, of the sleeve **123**. The flaps **124***a* and **124***b* open and close independent of each other, and are typically folded inward when the sleeve **123** is employed to at least partially cover a sling. The flaps **124***a* and **124***b* may be opened to assist the removal of the sleeve **123** from an associated sling.

In a similar fashion to the flapped section **125**, the flapped section **127** is formed from two transversely extending discontinuities **131***a* and **131***b* and a longitudinally extending cut/discontinuity **131***c*. The transversely extending discontinuities **131***a* and **131***b* interoperate with the longitudinally extending discontinuity **131***c* to divide the flapped section **127** into two flaps **126***a* and **126***b*. As in the case of the flaps **124***a* and **124***b*, the flaps **126***a* and **126***b* are anchored along the longitudinal edges **133***a* and **133***b*, respectively, of the sleeve **123**. The flaps **126***a* and **126***b* open and close independent of each other, and are folded inward when the sleeve **123**

is employed to at least partially cover a sling. They may be opened to facilitate removal of the sleeve **123** from the enclosed sling **121**. As configured in FIG. **6**, the sling **121** is located on top of the bottom layer of the sleeve **123**. With the flaps **124***a*, **124***b*, **126***a* and **126***b* closed, the sling **121** is essentially sandwiched between the top layer and the bottom layer of the sleeve **123** along the flapped sections **125** and **127** and is exposed along the tabbed end sections **129***a* and **129***b* and the gap **122**. According to this illustrative embodiment, the tangs of the sling **121** are covered in the protective sleeve **123**. The exposed portions of the sling **121** are non-tanged. The sling assembly **120** of this illustrative embodiment may be useful for delivering the sling, for example, **121** through an incision or incisions besides the vaginal incisions.

The sleeve of the invention may be made, for example, from one or more absorbent materials, such as a sponge-like material, which can optionally be pre-soaked in a drug solution, for example, in an anesthetic, anti-inflammatory, coagulating, anticoagulating, or antibiotic solution. In a preferred embodiment, the sleeve may be made from bio-compatible and flexible material. In another embodiment, the sleeve may be made from a non-wettable material, such as polypropylene, polyethylene, polyester, polytetrafluoroethylene (available from DuPont Corporation, Wilmington, Delaware, under the trademark TEFLON®), TYVEK®, MYLAR®, or co-polymers thereof. The non-wettable materials may also be pretreated with a therapeutically effective drug coating. The material of the sleeve may be a single layer or consist of multiple layers. The sleeve, preferably, is transparent so that an operator will be able to see the implantable sling inside the sleeve. The sleeve may be made of or include bioabsorable materials. Examples of bioabsorbable sleeves, and examples of materials for making such sleeves, are disclosed in commonly assigned U.S. patent application Ser. No. 10/631,364, the contents of which are incorporated herein by reference in their entirety.

The sling used with the invention may be fabricated from any of a number of biocompatible materials, such as nylon, polyethylene, polyester, polypropylene, fluoropolymers, copolymers thereof, combinations thereof, or other suitable synthetic material(s). The material may be, for example, a synthetic material that is absorbable by the patient's body. Suitable absorbable synthetic materials can include polyglycolic acid, polylactic acid, and other suitable absorbable synthetic materials. Alternatively, the material for the sling may be derived from mammalian tissue(s) or a combination of mammalian tissue(s) and synthetic material(s). The sling material may be fabricated from one or more yams, which yams may be made from one or more materials. The sling may incorporate or be coated with one or more agents to provide a therapeutic effect, for example, to reduce discomfort, to reduce the chance of infection and/or to promote tissue growth.

The edge regions of the sling used with the invention can be configured differently depending on their intended placement in the body of the patient. For example, a middle section of the sling is typically located where an anatomical site, such as a midurethral or bladder neck location in the periurethral tissue, needs to be supported. In one illustrative embodiment, the middle section of the sling has smooth or rounded edges, hereinafter also referred to as "non-tanged." According to a further illustrative embodiment, other sections of the sling may include tangs (e.g., sharp projections or frayed edges). The tangs are generally useful for anchoring the sling and encouraging tissue growth into the sling. Anchoring the sling in this manner generally obviates the need for additional sutures to hold the sling in place. Anchoring the sling via its tangs is especially useful for anchoring the sling on a tissue and facilitating the removal of the sleeve according to the invention by pulling on the center tab of the sleeve while the sling stays in place, without the need for additional incisions in order to hold the sling external to the body while the sleeve is being removed through pulling.

The tanged and non-tanged edges of the sling may be formed in a plurality of ways. For example, the sling can be cut from a woven sheet, in which case the edges would be initially tanged along the entire length of the sling. One or more non-tanged sections may be formed by any process that smoothes, rounds or removes the sharp edges of the tangs. For example, the tangs may be heat-smoothed by burning or melting the tangs. In one embodiment, the non-tanged section has a length of about 1 cm to about 5 cm, preferably about 2 cm to about 2.5 cm, on either or both sides of the center of the sling. Providing one or more non-tanged sections, which may be in close proximity to a sensitive anatomical site in the patient, can enhance the comfort level of the patient and reduce the potential for the edges of the tangs to erode or irritate the urethra. Alternatively, the sling can be produced from a woven tape having the approximate finished width of the sling. The smooth sides of the tape can then be trimmed off to produce the tanged sections.

FIG. **7** depicts an illustrative sling delivery system **200** for delivering a mesh sling **50** through a single incision such as, for example, a midline incision in a vaginal wall, according to an illustrative embodiment of the invention. As shown in FIG. **7**, the sling delivery system **200** includes a delivery device **130**, which is assembled with the sling assembly **11**. The sling assembly **11** includes the sleeve **10** and the sling **50**, as depicted in FIG. **2**. The delivery device **130** includes a handle **136** and a shaft **138** extending distally from the handle **136**. The shaft **138** includes a distal tip **134** for slidably interfitting with the sling end **146** of the sling **50**. The delivery device **130** also includes a pusher assembly **140**, which slidably interfits over the shaft **138** and abuts the distal end **148** of the handle **136**.

The distal end tip **134** of the delivery device **130** slides through a through aperture **24***a* of the sleeve **10** and through a mesh opening (or a through aperture) in the sling **50** until the sling **50** and the sleeve **10** rest on the shoulder **142** of the pusher assembly **140**. A distal end of the pusher assembly **140** forms a radially outwardly extending shoulder **142** around the circumference of the shaft **138** and functions to impede the sling end **146** from sliding proximally along a substantial portion of the length of the shaft **138**. The sling assembly **11** is oriented such that the top layer **14** of the sleeve **10** faces the urethra. A medical operator may use a thumb to hold the center tab **16** of the sling assembly **11** against the handle **136** of the delivery device **130** to maintain the sling assembly **11** hooked onto the delivery device **130** during insertion. The center tab **16** can be used as a visual aid to the placement of the sling assembly **11**. For example, after a midline incision is made, the sling assembly **11** is first advanced and directed through the midline incision on the right side of the patient until the center tab **16** of the sling assembly **11** is about underneath the urethra. Once the first end of the sling assembly **11** is placed at a desired anatomical location, the medical operator pushes the actuator **144** of the pusher assembly **130** in a distal direction, causing the shoulder **142** to push the sling end **146** distally off the distal tip **134** of the shaft **138**. Next, the same or a different delivery device **130** is inserted through the through aperture **24***b* of the sleeve **10** and through a mesh opening (or a through aperture) in the sling **50** and the same procedure described above is repeated to deliver the sling

assembly **11** on the left side of the patient. The sling ends may be delivered to any suitable location within the patient's body.

After the sling assembly **11** is positioned within the patient, the medical operator can simply pull the center tab **16** outward away from the incision. The non-sleeved, exposed tangs of the sling **50** have engaged the tissue on both ends of the sling assembly. By pulling the center tab **16** of the sleeve **10**, the flaps **32***a*, **32***b*, **36***a* and **36***b* on the top layer **14** of the sleeve **10** open while the sling **50** remains stationary. Continually pulling the center tab **16** removes the protective sleeve **10** away from the sling **50**. In this way, the sleeve **10** can be removed from the sling **50** from the same orifice through which the insertion of the sling assembly **11** is made, thus eliminating the need for any additional incision, such as an ishipubic incision or an abdominal incision, which is required for sleeve removal for currently available sling assemblies. As described above, the use of the sleeve **10** of the invention also eliminates the need for cutting the center tab **16** in order to remove the sleeve **10** from the sling **50**. Although FIG. **7** depicts the delivery of the sling assembly **11** including the sleeve **10**, other embodiments of the sleeves, including the sleeve **60** as depicted in FIGS. **3**A, **3**B, **4**A and **4**B, the sleeve **100** as depicted in FIG. **5**, can be used in the same manner.

Other suitable delivery devices may also be used with the sling assembly of the invention, including, for example, those described in U.S. application Ser. No. 10/973,010 entitled "Systems and Methods Relating to Anchoring a Medical Implant to Tissue" and filed on Oct. 25, 2004, and U.S. application Ser. No. 10/642,395 entitled "Systems, Methods and Devices Relating to Delivery of Medical Implants" and filed on Aug. 14, 2003, the entire contents of which are incorporated herein by reference.

As mentioned above, the sleeve of the invention enables the delivery of a sling assembly and removal of the sleeve through a single incision. The sleeve of the invention may also be used with embodiments in which the sleeve is used to deliver a sling through more than one incisions, including more than one vaginal incision, abdominal incision or ishiopubic incision. The sling may be delivered via abdominal, suprapubic, prepubic, transvaginal, transobturatoral or other approaches.

According to a transvaginal approach, the delivery device is advanced through an incision in the vaginal wall toward an abdominal incision on the right side of a patient until the first end of the sling assembly emerges from the abdominal incision. Then, the delivery device is withdrawn and the second end of the sling assembly is connected to the same or second delivery device, and inserted through the vaginal incision and advanced toward the abdominal incision on the left side of the patient until the second end of the sling assembly emerges from the abdominal incision or the ishiopubic incision.

According to an abdominal approach, the distal end of the delivery device is inserted into an abdominal incision down to a vaginal incision. The distal tip of the shaft then hooks a first end of the sling assembly. The shaft is then pulled back pulling the sling assembly through the path the shaft has created in the body of the patient until the first end of the sling assembly emerges at the abdominal incision. The same procedure is repeated with the second end of the sling assembly, with the same or different delivery device.

According to a transobtural approach, the shaft of the delivery device may be advanced through a vaginal incision toward an ishiopubic incision to deliver each sling end to a respective obturator foramen. Alternatively, the shaft of the delivery device may be advanced through an ishiopubic incision and through an incision in the vaginal wall. A sling assembly end may then be hooked on to the distal end of the shaft. The shaft can then be withdrawn to place each sling end in a respective obturator foramen. In other alternative procedures the sling ends attach to soft tissue anchors, which are left implanted in the patient's body to secure the sling in place.

After the placement of the sling assembly as described above, the sling assembly can be adjusted external to the body (instead of using the center tab to adjust the sling). The sleeve can then be removed via the vaginal incision by pulling on the center tab and opening up the flaps on the sleeve, while the sling ends may be held external to the body (instead of relying on the tangs of the sling to engage the tissue for the sling to remain stationary during the removal of the sleeve). Any embodiments of the sleeves in the application may be used to deliver a sling through more than one incisions as described above. Preferably, to minimize the irritation on the tissue that may be caused by exposed tangs on a sling during the placement procedure, the sling assembly **120** as depicted in FIG. **6**, with the tangs of the sling **121** completely enclosed in the sleeve **123**, is used for sling delivery through incisions besides the vaginal incision.

The invention described herein may be employed with any suitable sling or sling assembly, any suitable sling delivery device or approach, any suitable sling assembly-to-delivery device association mechanism, and any suitable anchoring mechanism or none at all.

Without limitation, examples slings, sling assemblies, sling delivery devices and approaches, sling assembly-to-delivery device association mechanisms, and sling anchoring mechanisms with which the invention may be employed disclosed in U.S. Pat. No. 6,042,534, entitled "Stabilization sling for use in minimally invasive pelvic surgery," U.S. Pat. No. 6,755,781, entitled "Medical slings," U.S. Pat. No. 6,666,817, entitled "Expandable surgical implants and methods of using them," U.S. Pat. No. 6,042,592, entitled "Thin soft tissue surgical support mesh," U.S. Pat. No. 6,375,662, entitled "Thin soft tissue surgical support mesh," U.S. Pat. No. 6,669,706, entitled "Thin soft tissue surgical support mesh," U.S. Pat. No. 6,752,814, entitled "Devices for minimally invasive pelvic surgery," U.S. Ser. No. 10/918,123, entitled "Surgical Slings," U.S. patent application Ser. No. 10/641,376, entitled "Spacer for sling delivery system," U.S. patent application Ser. No. 10/641,192, entitled "Medical slings," U.S. Ser. No. 10/641,170, entitled "Medical slings," U.S. Ser. No. 10/640,838, entitled "Medical implant," U.S. patent application Ser. No. 10/460,112, entitled "Medical slings," U.S. patent application Ser. No. 10/631,364, entitled "Bioabsorbable casing for surgical sling assembly," U.S. Ser. No. 10/092,872, entitled "Medical slings," U.S. patent application Ser. No. 10/939,191, entitled "Devices for minimally invasive pelvic surgery," U.S. patent application Ser. No. 10/774,842, entitled "Devices for minimally invasive pelvic surgery," U.S. patent application Ser. No. 10/774,826, entitled "Devices for minimally invasive pelvic surgery," U.S. Ser. No. 10/015,114, entitled "Devices for minimally invasive pelvic surgery," U.S. patent application Ser. No. 10/973,010, entitled "Systems and methods for sling delivery and placement," U.S. patent application Ser. No. 10/957,926, entitled "Systems and methods for delivering a medical implant to an anatomical location in a patient," U.S. patent application Ser. No. 10/939,191, entitled "Devices for minimally invasive pelvic surgery," U.S. patent application Ser. No. 10/918,123, entitled "Surgical slings," U.S. patent application Ser. No. 10/832,653, entitled "Systems and methods for sling delivery and placement," U.S. patent application Ser. No. 10/642,397, entitled "Systems, methods and devices relating to delivery of medical implants," U.S. patent application Ser. No. 10/642,395, entitled "Systems, methods and devices relating to delivery of

medical implants," U.S. patent application Ser. No. 10/642,365, entitled "Systems, methods and devices relating to delivery of medical implants," U.S. patent application Ser. No. 10/641,487, entitled "Systems, methods and devices relating to delivery of medical implants," U.S. patent application Ser. No. 10/094,352, entitled "System for implanting an implant and method thereof," U.S. patent application Ser. No. 10/093,498, entitled "System for implanting an implant and method thereof," U.S. patent application Ser. No. 10/093,450, entitled "System for implanting an implant and method thereof," U.S. patent application Ser. No. 10/093,424, entitled "System for implanting an implant and method thereof," U.S. patent application Ser. No. 10/093,398, entitled "System for implanting an implant and method thereof," and U.S. patent application Ser. No. 10/093,371, entitled "System for implanting an implant and method thereof," the entire contents of all of which are incorporated herein by reference.

What is claimed is:

**1**. A method for delivering a sling to periurethral tissue in a patient comprising: positioning a sling, covered at least partially by a sleeve, in the periurethral tissue, and removing the sleeve from the sling by unfolding the sleeve transversely, relative to the longitudinal axis of the sleeve, and away from the sling to deliver the sling to the periurethral tissue.

**2**. A method for delivering a sling to periuthral tissue in a patient through a single incision, comprising:

placing a sling, covered at least partially by a sleeve, in the periurethral tissue through a single incision, and

removing the sleeve away from the sling through the single incision to deliver the sling to the periurethral tissue, wherein the sleeve has a top layer, a bottom layer and a first and second longitudinal edges, the top layer including at least one portion having a longitudinally extending discontinuity forming at least flap-like structure anchored and freely pivotable along the first longitudinal edge of the sleeve.

**3**. The method of claim **2**, wherein the longitudinally extending discontinuity is located between the first and second longitudinal edges of the sleeve, forming at least first and second flap-like structures, the first flap-like structure being anchored and freely pivotable along the first longitudinal edge of the sleeve and the second flap-like structure being anchored and freely pivotable along a second longitudinal edge of the sleeve.

**4**. The method of claim **2**, wherein the top layer of the sleeve includes at least a first flapped section, a middle section and a second flapped section, the first flapped section having a first longitudinally extending discontinuity forming at least a first flap-like structure anchored and freely pivotable along a longitudinal edge of the sleeve, and the second flapped section having a second longitudinally extending discontinuity forming at least a second flap-like structure anchored and freely pivotable along a longitudinal edge of the sleeve.

**5**. The method of claim **2**, wherein the top layer of the sleeve includes at least a first flapped section and a second flapped section, the first flapped section having a first longitudinally extending discontinuity forming at least a first flap-like structure anchored and freely pivotable along a longitudinal edge of the sleeve, and the second flapped section having a second longitudinally extending discontinuity forming at least a second flap-like structure anchored and freely pivotable along a longitudinal edge of the sleeve, wherein the top layer of the sleeve further includes a gap between the first flapped section and the second flapped section.

**6**. A protective sleeve for an implantable supportive sling, the sleeve having a top layer, a bottom layer and first and second longitudinal edges, the top layer including at least one portion having a longitudinally extending discontinuity forming at least a flap-like structure anchored and freely pivotable along the first longitudinal edge of the sleeve; and

wherein the top layer of the sleeve includes at least a first flapped section and a second flapped section, the first flapped section having a first longitudinally extending discontinuity forming at least a first flap-like structure anchored and freely pivotable along a longitudinal edge of the sleeve, and the second flapped section having a second longitudinally extending discontinuity forming at least a second flap-like structure anchored and freely pivotable along a longitudinal edge of the sleeve, wherein the top layer of the sleeve further includes a gap between the first flapped section and the second flapped section.

**7**. The protective sleeve of claim **6**, wherein the first longitudinally extending discontinuity is located between the first and second longitudinal edges of the sleeve, forming two flap-like structures within the first flapped section, and the second longitudinally extending discontinuity is located between the first and the second longitudinal edges of the sleeve, forming two flap-like structures within the second flapped section.

**8**. The protective sleeve of claim **7**, wherein the first flapped section and the second flapped section each includes a transversely extending discontinuity extending between the first longitudinal edge and the opposing second longitudinal edge to divide the two flap-like structures into at least four flap-like structures, each being anchored and freely pivotable along a longitudinal edge of the sleeve.

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